ISOLATED LIMB PERFUSION (ILP) FOR MALIGNANT MELANOMA
SUR701.010

COVERAGE:

When used as a therapeutic treatment of local recurrence of nonresectable melanoma (i.e., satellite lesions or "in transit" melanoma), isolated limb perfusion with Melphalan may be ELIGIBLE FOR COVERAGE.

When used as an adjuvant treatment of surgically treated primary malignant melanoma with no clinical evidence of the disease, isolated limb perfusion with Melphalan is considered NOT MEDICALLY NECESSARY.

When used as an adjuvant treatment of surgically treated locally recurrent melanoma with no clinical evidence of disease. Isolated limb perfusion with Melphalan is considered investigational.

The addition of hyperthermia to isolated limb perfusion is considered INVESTIGATIONAL.

Isolated limb perfusion using Melphalan in conjunction with tumor necrosis factor is considered INVESTIGATIONAL.

DESCRIPTION:

Isolated Limb Perfusion (ILP) is a surgical procedure for the treatment or palliation of locally advanced malignant tumors of the extremity. It involves:

1. mobilization and placement of catheters into the major vessels (axillary, brachial, iliac or popliteal artery and vein) proximal to the tumor;

2. isolation of the limb via a tourniquet; and

3. perfusion of a chemotherapeutic drug via an extracorporeal circulation system into the affected extremity during a surgical procedure. Perfusion lasts for approximately 60-90 minutes. The procedure may be performed with or without hyperthermia and may be used as an alternative or adjunct to surgical excision of the tumor and resection of regional lymph nodes.

RATIONALE:

In the 1992 TEC assessment, there are currently no randomized controlled trials focusing on the therapeutic use of ILP as a treatment of locally recurrent melanoma that can not be surgically resected. However, large case series have consistently reported impressive complete response rates compared to systemic chemotherapy.

According to Balch, et al, there are no randomized controlled studies because there is currently no alternative therapy that would provide a meaningful comparison to ILP with Melphalan. In this population of patients with few treatment options, ILP with Melphalan is currently
considered the gold standard. Instead, research has focused on ways to enhance the results with ILP. There has been recent research interest in the use of tumor necrosis factor (TNF) as part of ILP. At the present time, TNF is not a U.S. Food and Drug Administration approved drug, and on this basis, the use of TNF in an ILP procedure is considered investigational.

Mild hyperthermia is often used in conjunction with ILP. However, there are no published controlled trials that compare the outcomes of ILP with or without hyperthermia. Retrospective analysis of case series suggest that there is no significant improvement when hyperthermia is added to the ILP regimen.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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